

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:  
Christian FRISCH et al.

Serial No.: Unassigned  
(based on Serial No. 09/795,872 filed 2/28/01)

Art Unit: Unassigned

Filed: September 16, 2003

Examiner: Unassigned

For: GENERATION OF SPECIFIC BINDING PARTNERS BINDING TO  
(POLY)PEPTIDES ENCODED BY GENOMIC DNA FRAGMENTS OR ESTs

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and 37 CFR §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

The documents submitted herewith on Form PTO/SB/08A, lists the documents cited by or submitted to the Patent Office in parent application Serial No. 09/795,872 filed February 28, 2001. The relevance of these prior art documents is explained in the parent application.

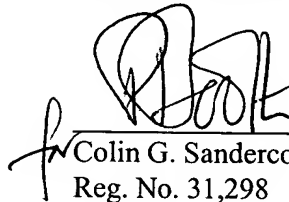
As provided in 37 C.F.R. §1.98(d), copies of the documents are not being provided since they were previously cited by or submitted to the Patent Office in parent application Serial No. 09/795,872 filed February 28, 2001.

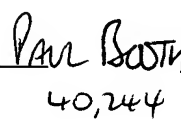
The instant Information Disclosure Statement is being filed within three months of the filing date under 37 CFR §1.97(b)(1), therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

September 16, 2003  
Date

  
for Colin G. Sandercock  
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

### Complete if Known

Application Number	Unassigned
Filing Date	September 16, 2003
First Named Inventor	Christian FRISCH et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	37629-0079

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A01	5,895,651		Simons et al.	4/1999	
	A02	5,814,477		Williams et al.	9/1998	
	A03	5,989,554		Knuth et al.	11/1999	

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A04	WO	98/30684			7/16/1998		

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		Attorney Docket Number	37629-0079		
Sheet	2	of	4		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A05	GUAN, C. et al., "Vectors that facilitate the expression and purification of foreign peptides in scherichia coli by fusion to maltosebinding protein", Gene, 1988, Vol. 67, pp. 21-30	
	A06	MAINA, C.V. et al., "An Escherichia coli vector to express and purify foreign proteins by fusion to and separation from maltosebinding protein", Gene, 1988, Vol. 74, pp. 367-373	
	A07	RUDOLPH, R. et al., "In vitro folding of inclusion body proteins", FASEB J., 1996, Vol. 10, pp. 49-56	
	A08	MARCZINOVITS, I. Et al., "An alternative purification protocol for producing hepatitis B virus X antigen on a preparative scale in Escherichia coli", J. Biotechnology, 1997, Vol. 56, pp. 81-88	
	A09	NANDI, A. et al., "Expression of the Extracellular Domain of the Human Heat-Stable Enterotoxin Receptor in Escherichia coli and Generation of Neutralizing Antibodies", Protein Expression and Purification, 1996, Vol. 8, pp. 151-159	
	A10	VAUGHAN, T.J., et al., "Human Antibodies with Sub-nanomolar Affinities Isolated from a large Non-immunized Phage Display Library", Nature Biotech., 1996, Vol. 14, pp. 309-314	
	A11	C. KREBBER et al., "Selectively-infective phage (SIP): A mechanistic dissection of a novel in vivo selection for protein-ligand interactions", J. Mol. Biol., 1997, Vol. 268, pp. 607-618	
	A12	L. PERSIC et al., "Single-chain variable fragments selected on the 57-76 p21 Ras neutralizing epitope from phage antibody libraries recognize the parental protein", FEBS Letters, 1999, Vol. 443, pp. 112-116	
	A13	Y. HITOMI et al., "High efficiency prokaryotic expression and purification of a portion of the Hepatitis C core protein and analysis of the immune response to recombinant protein in BALB/c mice", Viral Immunology, 1995, Vol. 8, pp. 109-119	
	A14	G. HAGENDORFF et al., "A monoclonal antibody generated against a recombinant peptide fragment of the B3 domain of carcinoembryonic antigen reacts with intact carcinoembryonic antigen", Biochemica et Biophysica Acta, 1995, Vo. 1260, pp. 259-268	

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	A15	H. TAKEMURA et al., "Cloning and expression of human defensin HNP-1 genomic DNA in Escherichia coli", <u>Journal of Microbiological Methods</u> , 1996, Vol. 25, 287-293	
	A16	R. RUDOLPH and H. LILIE, "In vitro folding of inclusion body proteins", <u>The FASEB Journal</u> , 1996, Vol. 10, pp. 49-56	
	A17	JEAN-MICHEL BETTON et al., "Folding of a Mutant Maltose-binding Protein of Escherichia coli Which Forms Inclusion Bodies", <u>The Journal of Biological Chemistry</u> , April 5, 1996, pp. 8046-8052, Vol. 271, No. 14, The American Society for Biochemistry and Molecular Biology, Inc.	
	A18	DEB K. CHATTERJEE et al., "Cloning and overexpression of the gene encoding bacteriophage T5 DNA polymerase", <u>Gene</u> , 1991, pp. 13-19, Vol. 97, Elsevier Science Publishers	
	A19	GLEN A. COBURN et al., "Overexpression, Purification, and Properties of Escherichia coli Ribonuclease II", <u>The Journal of Biological Chemistry</u> , January 12, 1996, pp. 1048-1053, Vol. 271, No.2, The American Society for Biochemistry and Molecular Biology, Inc.	
	A20	NIEK DEKKER et al., "In vitro folding of Escherichia coli outer-membrane phospholipase A", <u>Eur. J. Biochem.</u> , 1995, pp. 214-219, Vol. 232, FEBS	
	A21	ALAN I. DERMAN et al., "Escherichia coli Alkaline Phosphatase Localized to the Cytoplasm Slowly Acquires Enzymatic Activity in Cells Whose Growth Has Been Suspended: a Caution for Gene Fusion Studies", <u>Journal of Bacteriology</u> , July 1995, pp. 3764-3770, Vol. 177, No. 13, American Society for Microbiology	
	A22	JAN-OLOV HÖÖG et al., "Nucleotide sequence of the thioredoxin gene from Escherichia coli", <u>Bioscience Reports</u> , 1984, pp. 917-923, Vol. 4, The Biochemical Society, Great Britain	
	A23	ROBERT KUHELJ et al., "The preparation of catalytically active human cathepsin B from its precursor expressed in Escherichia coli in the form of inclusion bodies", <u>Eur. J. Biochem.</u> , 1995, pp. 533-539, Vol. 229, FEBS	
	A24	URSULA RINAS et al., "Overexpression of Bacterial Hemoglobin Causes Incorporation of Pre-β-Lactamase into Cytoplasmic Inclusion Bodies", <u>Appl. Environ. Microbiol.</u> , February 1993, pp. 561-566, Vol. 59, No. 2, American Society for Microbiology	

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	A25	KOEN VANDENBROECK et al., "Refolding and single-step purification of porcine interferon-γ from Escherichia coli inclusion bodies Conditions for reconstitution of dimeric IFN-γ", Eur.J.Biochem., 1993, pp. 481-486, Vol. 215, FEBS	
	A26	S. MAKRIDES, "Strategies for Achieving High-Level Expression of Genes in Escherichia Coli", Microbiological Review (1996) 512-538.	
	A27	C. SCHEIN, "Solubility as a function of protein structure and solvent components", Bio/Technology vol. 8, (1990) 308-317	
	A28	D. WILKINSON et al., "Predicting the solubility of recombinant proteins in escherichia coli", Bio/Technology vol. 9 (1991) 443-448	

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